REMARKS

Claims 1-26 were pending before entry of the present amendment. Claim 18 has been canceled without prejudice. Applicants reserve their right to prosecute the subject matter of claim 18 in one or more related divisional, continuation or continuation-in-part applications. Claim 2 has been amended to recite that the RNA-directed RNA polymerase is a viral RNA-directed RNA polymerase. Support for the amendment to claim 2 can be found at page 12, line 26 of the specification as filed. The amendment to claim 2 merely clarifies the subject matter intended to be claimed, and in no way narrows the scope of the claims. Claim 13 has been amended to incorporate the limitations of former claim 18. New claims 27 and 28 have been added. Support for new claims 27 and 28 can be found in the Specification as originally filed, *e.g.*, at page 55, line 1 through page 63, line 36. Thus, no new matter has been introduced. Upon entry of the present amendment, claims 1 to 17 and 19 to 28 will be pending.

The Double Patenting Rejection of Claims 1, 13, and 25 Should Be Withdrawn

Claims 2, 13, and 25 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 6 and 7 of U.S. Patent No. 5,840,520 (the "'520 patent"). In particular, the Examiner contends that claims 2, 13, and 25 of the present application are not patentably distinct from claims 6 and 7 of the '520 patent because limitations of the present claims are described in the specification of the '520 patent. Applicants respectfully disagree because the disclosure of the patent underlying the double patenting rejection may not be used as prior art against the claims under consideration. See M.P.E.P. 804(II)(B)(1).

Claims 6 and 7 of the '520 patent are directed to chimeric viruses comprising a respiratory syncytial virus containing a heterologous RNA sequence comprising the reverse complement of an mRNA coding sequence, operatively linked to a respiratory syncytial viral polymerase binding site or a polymerase binding site of the respiratory syncytial virus, respectively. Claims 2 and 25 of the present application are directed to isolated infectious RSV containing an RSV RNA comprising a binding site specific for an RNA-directed RNA

polymerase operatively linked to an RSV RNA comprising sequence encoding antigenic polypeptides of both RSV-A and RSV-B. Claim 13, after entry of the present amendment, is directed to vaccines comprising a chimeric RSV the genome of which contains the reverse complement of an mRNA coding sequence operatively linked to a polymerase binding site of an RSV and a pharmaceutically acceptable carrier, wherein the mRNA coding sequence encodes G and F polypeptides of both Respiratory Syncytial Virus A and Respiratory Syncytial Virus B. Thus, the claims of the present application are distinguished over the claims in the '520 patent by the limitation that the RSV RNA comprises a sequence encoding polypeptides of both RSV-A and RSV-B.

The standard for determining whether an obviousness-type double patenting rejection is proper is whether:

> [A] person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent. When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. (Emphasis added).

See M.P.E.P. 804(II)(B)(1). "[A]ny analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination." See M.P.E.P. 804(II)(B)(1). A finding of obviousness under § 103 requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere* 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggests the invention, and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. *In re O'Farrell* 853 F.2d 894, 903 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art and not in the Applicants' disclosure. In re Vaeck 947 F.2d 488 (Fed. Cir. 1991). Further, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." See M.P.E.P. 2142.

The claims in issue are not obvious variations of claims 6 and 7 of the '520 patent because the claims in issue recite additional claim limitations that are not recited by the claims of the '520 patent. Importing the additional limitations of the claimed invention from the specification of the '520 patent would be identical to applying the specification of the '520 patent as a prior art reference under 35 U.S.C. § 103. However, as stated above, the specification of the patent underlying the double-patenting rejection cannot be used as prior art reference. See M.P.E.P. 804(II)(B)(1). Applicants therefore respectfully request that the obviousness-type double patenting rejection of claims 2, 13 and 25 over claims 6 and 7 of the '520 patent be withdrawn.

The Provisional Double Patenting Rejection

Claims 2, 13, and 25 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 25 to 27 and 32 of copending application 09/923,070. As this is a provisional double-patenting rejection, Applicants will not address the rejection on its merits at this time.

The Double Patenting Rejection of Claim 13 Should Be Withdrawn

Claim 13 was rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 12 of U.S. Patent No. 5,820,871 (the "'871 patent"), and claims 1 and 16 of U.S. Patent No. 5,166,057 (the "'057 patent"). In particular, the Examiner contends that claim 13 of the present application is not patentably distinct from claims 1 and 12 of the '871 patent, and claims 1 and 16 of the '057 patent because the specifications of the patents indicate that RSV can be used as a negative strand RNA virus. Applicants respectfully disagree because the disclosure of the patent underlying the double patenting rejection may not be used as prior art against the claims under consideration. See M.P.E.P. 804(II)(B)(1).

Claim 13 is directed to vaccines comprising an RSV the genome of which contains the reverse complement of an mRNA coding sequence operatively linked to a polymerase binding site of an RSV and a pharmaceutically acceptable carrier, wherein the

mRNA coding sequence encodes G and F polypeptides of both Respiratory Syncytial Virus A and Respiratory Syncytial Virus B. Claims 1 and 12 of the '871 patent, and claims 1 and 16 of the '057 are directed to compositions comprising a binding site specific for an RNA-directed RNA polymerase of a negative strand RNA virus, operatively linked to a heterologous RNA sequence comprising the reverse complement of an mRNA coding sequence. Claim 13 of the present application recites the limitation that the claimed vaccine comprises a chimeric RSV, encoding sequences from both RSV-A and RSV-B, and therefore differs from claims 1 and 12 of the '871 patent, and claims 1 and 16 of the '057 patent.

The claims in issue recite claim limitations that are not obvious variations of claims 1 and 12 of the '871 patent, and claims 1 and 16 of the '057 patent. Importing those limitations from the specifications of the '871 or the '057 patent would be identical to applying those specifications as a prior art references under 35 U.S.C. § 103. However, as stated above, the specification of the patent underlying the double-patenting rejection cannot be used as prior art reference. See M.P.E.P. 804(II)(B)(1). Applicants therefore respectfully request that the obviousness-type double patenting rejection of claim 13 over claims 1 and 12 of the '871 patent, and claims 1 and 16 of the '057 patent be withdrawn.

The Double Patenting Rejection of Claim 2 Should Be Withdrawn

Claim 2 was rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over either claims 1 and 12 of the '871, or claims 1 and 16 of the '057 patent, in view of U.S. Patent 6,033,668 issued to Klein *et al.* ("Klein"). In particular, the Examiner alleges that Klein teaches that RSV-A and RSV-B are major viral pathogens.

As discussed above, the specification of the patent(s) underlying the double patenting rejection may not be used as prior art references. See M.P.E.P. 804(II)(B)(1). Thus, all limitations of the claims in issue must be found in the claim in issue in combination with any prior art reference cited.

Claim 2 of the present application is drawn to a RSV RNA comprising a sequence encoding polypeptides of both RSV-A and RSV-B and as such is distinguished over

claims 1 and 12 of the '871 patent, or claims 1 and 16 of the '057 patent. To establish a *prima facie* case of obviousness, the limitation that the RSV RNA comprises a sequence encoding polypeptides of both RSV-A and RSV-B would have to be taught by Klein. Klein, however, does not teach this limitation. Klein teaches hybrid genes comprising a gene sequence coding for an immunogenic region of a protein from a first pathogen linked to a gene sequence coding for an immunogenic region of a protein from a second pathogen (column 2, line 65 to column 3, line 3). Klein further mentions that PIV types 1, 2 and 3, and RSV types A and B are major viral pathogens. While, Klein teaches that the first pathogen can be PIV and the second pathogen is RSV (column 3, lines 12-14), Klein does not disclose that a polypeptide from RSV-A can be combined with a polypeptide from RSV-B. Further, Klein does neither teach nor suggest that any RSV sequences can be part of the genome of an infectious RSV particle.

Thus, as Klein fails to teach or suggest the claim limitation that the RSV RNA comprises a sequence encoding polypeptides of both RSV-A and RSV-B, claim 2 in issue is not obvious over claims 1 and 12 of the '871 patent, or claims 1 and 16 of the '057 patent, and the rejection should be withdrawn.

The Rejection of Claims 2, 13, 25, and 26 under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

Claims 2, 13, 25, and 26 were rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. The claims, because they recite "an RNA-directed RNA polymerase", read on isolated RSV wherein the binding site specific for an RNA-directed RNA polymerase is other than a binding site for RSV RNA-directed RNA polymerase. The Examiner contends that the application does not provide any examples of RNA directed RNA polymerases other than RSV RNA-directed RNA polymerase.

Applicants respectfully point out that claim 13 recites a polymerase binding site of an RSV. The rejection under 35 U.S.C. § 112, first paragraph, therefore does not apply to claim 13.

With respect to claims 2, 25 and 26, Applicants respectfully direct the Examiner's attention to page 17, line 22, of the specification as filed, which provides an example of an RNA-directed RNA polymerase binding site other than RSV, namely influenza viral polymerase binding site. Further, at page 19, lines 24 to 25, the specification teaches that an influenza viral polymerase protein can be used with the invention. Thus, an example other than RSV RNA-directed RNA polymerase is provided.

Furthermore, Applicants respectfully direct the Examiner's attention to the specification which provides, at page 12, lines 26 of the specification as filed, that a viral RNA-directed RNA polymerase can be used to express the heterologous gene. The skilled artisan would have known that in order to use a viral RNA-directed RNA polymerase for the expression of the heterologous gene, the binding site must be the binding site of the respective viral RNA-directed RNA polymerase. Therefore, Applicants were in possession of the genus of viruses that encompass a viral RNA-directed RNA polymerase.

To comply with the written description requirement, description of a representative number of species is required.

> What constitutes a 'representative number' is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

M.P.E.P. 2163(II)(A)(3)(a)(ii) and M.P.E.P. 2163.05(I). Applicants respectfully submit that the skilled artisan would recognize that Applicants were in possession of the invention when the application was filed because the necessary common feature of the polymerase to be used with the invention, *i.e.*, that the polymerase be an RNA-directed RNA polymerase, was provided in the specification. Further, Applicants provided the description of at least two different RNA-directed RNA polymerases from RSV and influenza. Therefore, Applicants assert that the specification as filed provides sufficient written description support for the claim limitation of "a viral RNA-directed RNA polymerase."

Thus, Applicants did provide written description for using the genus of all viral RNA-directed RNA polymerases with the compositions and methods of the invention, and the rejection should be withdrawn.

CONCLUSION

Applicants respectfully request entry and consideration of the foregoing amendments and remarks. No new matter has been introduced. The claims are believed to be free of the art and patentable. Withdrawal of all the rejections and an allowance are earnestly sought.

Respectfully submitted,

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